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The goals of the study are to evaluate the role of paravertebral block regional anesthesia in patients undergoing operative treatment of breast cancer. Experience to date has shown that this anesthetic modality is safe and effective, and associated with excellent postoperative pain control and minimization of nausea and vomiting associated with general anesthesia. Using a prospective randomized trial carried out at three institutions, we propose to measure quality of life variables including pain, postoperative nausea and vomiting, mood, and functional status in patients undergoing breast surgery with the traditional techniques of general anesthesia versus the regional technique of paravertebral block. The preliminary phase of this trial, which establishes safety and efficacy in performing the block technique, is ongoing. Once adequate experience in performing the paravertebral block is obtained, we will initiate the study portion of the trial by randomizing patients undergoing surgery to either general anesthesia or paravertebral block. Outcomes will be assessed using validated study instruments, which are included with the report.

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FOREWORD

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X For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

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Chris Wells 5/1/00

PI - Signature Date

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INTRODUCTION

General anesthesia is currently the standard anesthetic technique used for modified radical mastectomy, lumpectomy with axillary dissection, and other major operations performed for the treatment of breast cancer. While general anesthesia ensures tolerance of the operative procedure, it is associated with a high incidence of postoperative nausea and vomiting in patients undergoing breast surgery and it is not capable of providing pain relief following emergence. Treatment of pain with parenteral narcotics and supportive care of postoperative nausea prolong hospitalization and diminish quality of life following breast cancer surgery. Paravertebral block is a regional anesthetic technique used historically for the diagnosis and treatment of chronic somatic pain and for operative procedures for the chest and shoulder. The concept of using paravertebral block anesthesia for breast surgery was introduced at Duke University Medical Center in 1994 with the goals of providing safe and effective anesthesia, prolonged postoperative pain relief, reduced nausea and vomiting, and thus improved quality of life following surgical treatment of breast cancer. Retrospective review of a three-year experience with this technique has shown that these goals are being realized. The block provides effective anesthesia in 85% of cases and has a low complication rate of 2.6%. The technique provides sensory block that persists for an average of 23 hours, and therefore the patient experiences minimal surgical pain. Compared to general anesthesia, inpatient narcotic use in those undergoing paravertebral block is reduced from 98% to 25% while anti-emetic medication use is reduced from 39% to 20%. Patient satisfaction is high, hospital stays are shortened, and we now consider paravertebral block the anesthetic of choice for operative treatment of breast cancer. To test this hypothesis, we propose a prospective randomized clinical trial comparing general anesthesia and paravertebral block. The protocol for this trial will be designed such that all aspects of perioperative patient care other than the anesthetic used during surgery will be uniform. Narcotic, anti-emetic, and other medication use and responses to questionnaires will measure pain, nausea, mood, and other quality of life outcomes during the postoperative interval. Our goal is to definitively evaluate paravertebral block anesthesia in this application and to facilitate widespread use of a new technique that will markedly improve quality of life for most patients with breast cancer.

BODY

Task 1 as outlined in our original approved Statement of Work is to establish proficiency on the part of participating anesthesiologist in performing the paravertebral block. In April of 1999, Dr. Victor Moreno from the Department of Anesthesiology at Mount Sinai Medical Center traveled to Duke University Medical Center to study the paravertebral block technique. Under the supervision of Dr. Roy Greengrass, Dr. Moreno attained preliminary proficiency sufficient to perform these blocks independently and to train other anesthesiologist at his institution. During the subsequent months, Dr. Moreno and colleagues performed ten paravertebral blocks at Mount Sinai Medical Center on patients undergoing either modified radical mastectomy or lumpectomy with axillary lymph node dissection for the surgical treatment of breast cancer. The efficacy rate of these blocks has been 70%; in three cases conversion to general anesthesia was required due to inadequate block at all levels. Dr. Moreno and his colleagues were in communication with Dr. Greengrass to understand the problems they were having with achieving adequate block at all levels, and this has resulted in an improved understanding of the performance in this technique. No complications have been encountered in performing these preliminary blocks, including pneumothorax, infection, intravascular injection of local anesthetic, or epidural spread. Unfortunately, in January 2000, Dr. Moreno departed the faculty of Mount Sinai Medical Center Department of Anesthesiology. This has led to a delay in scheduled progress according to the original Statement of Work. One of Dr. Moreno's colleagues, Dr. Janet Pittman from the Department of Anesthesiology at Mount Sinai Medical Center has taken Dr. Moreno's place in leading this study protocol at our center from the anesthesia prospective. Dr. Pittman has also studied the paravertebral technique under Dr. Greengrass' supervision at Duke University. She will now be employing this technique at Mount Sinai to establish both safety and efficacy; and she will be training two colleagues in the performance of this technique under her supervision. Because of this change in personnel, we anticipate that Task 2 as outlined in the original Statement of Work will commence in August of 2000. Accordingly we are requesting from the U.S. Army Grant Administrator a one-year extension to the schedule of this trial.

In addition to the departure of Dr. Moreno, there has also been a significant departure of participating personnel within the surgical faculty at Mount Sinai, and this has reduced the anticipated number of patients that will be able to be recruited into the trial at this center. We have therefore extended the clinical trial to include a third participating center, the Medical University at South Carolina (MUSC). Headed by Dr. Mia Templeton of the Department of Anesthesiology, faculty at MUSC are being trained by Dr. Greengrass to perform this technique. The experience at this center is incipient, and to date we do not have safety or efficacy data to report. We anticipate that MUSC will be able to initiate Task 3 of the Statement of Work in August 2000. The anesthesia team at Duke University Medical Center does have extensive experience in the placement of paravertebral blocks. In addition to training personnel at the other medical centers,

they are prepared for the initiation from Task 3 of this trial. Again we anticipate the commencement of that phase in August of 2000.

Task 2 of our original Statement of Work centers on the preparation of study materials and the training of study personnel to execute the randomized clinical trial. In 1999, a clinical research group with expertise in biobehavioral medicine related to the treatment of cancer joined the faculty at the Ruttenberg Cancer Center at Mount Sinai, headed by Dr. Dana Bovbjerg. This group, particularly Dr. Guy Montgomery, has worked closely with the principal investigator of this trial to modify and streamline the series of study questionnaires which will be used to assess postoperative pain, nausea and vomiting, mood and functional status, and quality of life in patients entering this study protocol. The changes which have been made employ validated study questionnaires which address these issues and yet are not excessively cumbersome for patients to answer during the seven day postoperative interval. These study questionnaires do deviate from the initial questionnaires included in our grant proposal, and they are attached to this document. They will be employed according to the schedule outlines in the appendix to this report.

Task 3 of the original Statement of Work involves recruitment and randomization of subjects into the study protocol; execution of the study protocol; and completion of study questionnaires. No significant changes have been made to this core portion of our trial period. As mentioned above, we will have three participating medical centers. We have the same goal of recruiting two hundred patients between these study centers. The randomization process, performance of the surgery using either general anesthesia or the paravertebral block, and collection of postoperative surgical and anesthesia related data remains unchanged relative to our initial Statement of Work. As described above, the specific study questionnaires that patients will be asked to complete during the postoperative interval have been modified.

The final Task 4 of the Statement of Work, which involves data analysis and preparation of reports, remains unchanged relative to our initial proposal. Statistical analysis will be performed at the Ruttenberg Cancer Center at Mount Sinai.

KEY RESEARCH ACCOMPLISHMENTS

There is no data to report at this time. Key research accomplishments will be included in the final report.

REPORTABLE OUTCOMES

There is no data to report at this time. Reportable outcomes will be included in the final report.

CONCLUSIONS

At this time there are no study conclusions to report. These will be included with our final report.

APPENDIX

Included in this section are the new study questionnaires that will be used to measure postoperative pain, nausea and vomiting, mood and functional status, and quality of life for this study protocol.

The format of the patient questionnaire was revised pursuant to consultation with Dr. Guy Montgomery, an Assistant Professor and specialist in behavioral medicine with the Mount Sinai Ruttenberg Cancer Center. The revised format contains five sections.

Section one will be completed by the patient one week prior to surgery. This section records patient demographic data and medical history, and provides a baseline evaluation of mood, functional status, quality of life, and daily pain. Mood, functional status, and quality of life will be measured using a modified Profile of Mood States (POMS), and the Functional Assessment of Cancer Therapy – Breast (FACIT-B). Pain assessment will be made using a modified form of the Brief Pain Inventory (BPI) and a Visual Analog Scale (VAS).

Section two will be completed immediately prior to surgery. This section will include the POMS and a VAS for measurement of mood and emotional upset, and will be completed by the patient with help from a clinical nurse.

Section three will be completed immediately following surgery. This section will include a modified version of the Memorial Symptom Distress Assessment (MSDA), a VAS to measure pain and nausea, and the BPI. Section three will likewise be completed with help from a clinical nurse.

Section four is a daily questionnaire that will commence 24 hours postoperatively and continue for six days. This section will be completed either in the recovery room or by telephone once the patient has returned home. The daily questionnaire will include a record of patient postoperative narcotic usage, as well as the BPI, MSDA, and a VAS for the assessment of pain and nausea.

Section five will be completed on postoperative day number seven. This section will include final VAS, BPI, MSDA, POMS, and FACIT forms, as well as a Mount Sinai Medical Center Patient Satisfaction questionnaire.

PVB Study
Take Home
Questionnaire Packet

ID # _____

Date ____/____/_____

PERSONAL DATA

1. Today's date: ___ ___/ ___ ___/ ___ ___ (m/d/y)

2. Birth date: ___ ___/ ___ ___/ ___ ___ (m/d/y)

3. Height: _____ (ft) _____ (in)

4. Weight: _____ (pounds)

5. Ethnic group (circle one number):

1 White (non-Hispanic)
2 White (Hispanic)
3 Black (non-Hispanic)
4 Black (Hispanic)
5 Asian/Indian
6 Asian or Pacific Islander
7 Native American
8 Other _____
9 Unknown

6. Marital status (circle one number):

1 Never married
2 Currently married
3 Separated
4 Divorced
5 Widowed

7. Who lives with you? (circle all that apply):

1 No one
2 Spouse or partner
3 Roommate(s) (not a partner)
4 Parent(s)
5 Children
6 Other relatives
7 Other _____

8. How long have you lived with the people you live with now? (circle one number):

1 Less than 1 month
2 One to 6 months
3 Seven months to 2 years
4 Two to 5 years
5 More than 5 years

9. Level of school completed? (circle one number):

1 Less than 7th grade
2 Junior High school (9th grade)
3 Partial high school (10th or 11th grade)
4 High school graduate
5 Partial college or specialized training
6 Standard college or university graduate
7 Graduate professional training (graduate degree)

10. Current employment situation (circle one number):

A. WORKING

1 Full time at job
2 Part time at job

B. ON LEAVE

3 On leave with pay
4 On leave without pay

C. NOT EMPLOYED

5 Seeking work
6 Not seeking work
7 Receiving disability
8 Not self-supporting
9 Homemaker
10 Retired

D. STUDENT

11 Full time
12 Part time

11. Which category best describes your occupation? If you are not currently employed, which best describes your **LAST** job? If you are a homemaker, which best describes your spouse's usual occupation? (circle one number)

1. Professional, Technical, & Related Occupations (as teachers/professors, nurses, lawyers, physicians, & engineers)
2. Manager, Administrator, or Proprietor (as sales managers, real estate agents, or postmasters)
3. Clerical & Related Occupations (as secretaries, clerks or mail carriers)
4. Sales Occupations (as sales persons, demonstrators, agents & brokers)
5. Service Occupations (as police, cooks, or hairdressers)
6. Skilled Crafts, Repairer, & Related Occupations (as carpenters, repairers, or telephone line workers)
7. Equipment or Vehicle Operator & Related Occupations (as drivers, railroad brakemen or sewer workers)
8. Laborer (as helpers, longshoreman, or warehouse workers)
9. Farmer (owners, managers, operators or tenants)
10. Member of the military
11. Other (please describe) _____

12. Approximate annual gross income for your household: (circle one number)

1 Less than $ 10,000
2 $10,000 - $19,999
3 $20,000 - $ 39,999
4 $40,000 - $59,999
5 $60,000 - $100,000
6 Greater than $100,000

13. Do you own a home (apartment, house, country house, etc.)? (circle one): YES NO

14. Would you be able to pay off all of your debts if you sold everything that you own? (circle one): YES NO

(Remember, all information will be used for statistical purposes only)

Circle either "YES" or "NO"

15. Do you see a religious counselor on a regular basis? (circle one) YES NO

If yes, how many times in the last month? _____

16. Do you see a professional counselor or therapist on a regular basis? (circle one) YES NO

If yes, how many times in the last month? _____

17. Do you participate in any support or therapy group? (circle one) YES NO

If yes, how many times in the last month? _____

18. Were you practicing relaxation, meditation, or yoga before starting this study?(circle one) YES NO

19. Do you keep a diary? (circle one) YES NO

20. In general, how is your health compared to other people your age? (circle one)

EXCELLENT VERY GOOD GOOD FAIR POOR

21. Which hand do you use to write with? (circle one) LEFT RIGHT

22. Do you consider yourself left or right handed? (circle one) LEFT RIGHT

23. Over the past several years how much sleep do you normally get each night?

_____ hr _____ min

24. Over the past several years how much sleep per night have you needed to feel at your best?

_____ hr _____ min

25. Do you have a dog or a cat as a pet? (circle one) YES NO

26. What religion do you consider yourself a member of (please write in answer, write "none" if appropriate)?

_____

27. Where were you born? _____ (city, state, country)

FAMILY HISTORY OF CANCER

We are interested in knowing as much as possible about cancer in your biological relatives. On the following form, please indicate your relatives, what type of cancers they had, how old they were at the time of their diagnosis, as well as your age at that time. Please answer to the best of your knowledge. Approximate ages are useful if you cannot be exact, for example, "60's or 70's". Put "?" if you are not sure.

NOTE: Please list separately each cancer for each biological relative. (Please see examples in shaded areas).

	First Cancer			Second Cancer				
Relative Code (see bottom)	Location or Type of Cancer	Their Age at Diagnosis	Your Age Then	Location or Type of Cancer	Their Age at Diagnosis	Your Age Then	Outcome: Died from cancer? Yes (Y) No (N)	Were Both Breasts Affected?
1	Breast	55	26	Ovarian	65	36	N	No
6	Colon	40	18				Y	

1 = your mother
2 = your sister
3 = your daughter
4 = mother's mother
5 = mother's father
6 = mother's sister
7 = mother's brother
8 = mother's first cousin
9 = other (on mother's side)
10 = your father
11 = your brother
12 = your son
13 = fathers' mother
14 = father's father
15 = father's sister
16 = father's brother
17 = father's first cousin
18 = other (on father's side)
19 = your cousin (mother's side)
20 = your cousin (father's side)

Please note that this information is very important and will be kept confidential. Please also take your time completing this form.

☐ CHECK THIS BOX IF NO FAMILY HISTORY OF CANCER

MEDICAL HISTORY

1. How many times have you been seen by a doctor during the past year for any reason? (check best answer)
   _____ None _____ 1 time _____ 2-5 times _____ 6-12 times _____ over 12 times

2. When was the last time you had a complete physical examination?
   _____ Within the last year _____ 1-2 years ago _____ 2-5 years ago _____ over 5 years ago

3. When was the last time you had a mammogram?
   _____ Within the last year _____ 1-2 years ago _____ 2-5 years ago _____ over 5 years ago
   _____ Never had one

4. During your lifetime, have you smoked at least 100 cigarettes (5 packs)?
   ____ Yes _____ No **(Skip to Question 5)**

   If you answered YES to Question 4,

   a) At what age did you begin smoking regularly? _____ Age in years
   b) How many cigarettes do/did you regularly smoke each day? _____ Cigarettes
   c) Have you smoked in the past month?
      _____ Yes, approximately _____ cigarettes per day.
      _____ No, I quit approximately _____ years ago.

5. Have you consumed any alcoholic beverages in the past month?
   _____ Yes _____ No **(Skip to Question 6)**

   If you answered YES to Question 5, which of the following best describes how many alcoholic beverages you consumed in the past month?

   (Note: Beer: 1 can = 1 drink; Wine: 1 glass = 1 drink; Hard Liquor: 1 shot = 1 drink)

   _____ 1 drink a month
   _____ 2-3 drinks a month
   _____ 1-2 drinks a week
   _____ 3-4 drinks a week
   _____ 1 drink nearly every day
   _____ 1 drink a day
   _____ 2 drinks a day
   _____ 3 or more drinks a day

Circle either "YES" or "NO"

6. To your knowledge, have you ever been exposed to asbestos, solvents, or other industrial chemicals? YES NO

7. Have you ever been disabled for more than 2 months? YES NO

8. Have you had surgery in the last 6 months? YES NO
   If yes, when? Date(s):_____
   For what? _____

9. Have you had a biopsy for any cancer? YES NO
   If yes, when? Date(s):_____
   For what? _____

10. Have you ever had a disease lasting longer than 2 months? YES NO
    If yes, when? Date(s):_____
    What? _____

11. Do you take any medication regularly? Yes No

	Drug	Dose	How Often?	Since
(EXAMPLE)	___Tylenol_____	___2 capsules__	_twice daily__	_June, 1995_
(Pain)	_____	_____	_____	_____
(Heart)	_____	_____	_____	_____
(Birth Control)	_____	_____	_____	_____
(Hormones)	_____	_____	_____	_____
(Other)	_____	_____	_____	_____
(Other)	_____	_____	_____	_____
(Other)	_____	_____	_____	_____
(Other)	_____	_____	_____	_____

13. Are you now having or have you ever had:

Chemotherapy	Yes	No
Radiation therapy	Yes	No
Cortisone	Yes	No

14 Do you consider yourself (circle):

Premenopausal (Continue to get periods)	Postmenopausal (Do not get periods)	Not sure

15. Below are some situations which can cause some people to feel nauseated and/or to vomit. Please indicate if any of these situations have made <u>you</u> feel nauseated or caused you to vomit by checking one or both columns.

	Nausea has occurred with this item	Vomiting has occurred with this item
Pregnancy	_____	_____
Motion sickness	_____	_____
Drinking alcohol	_____	_____
Anxiety	_____	_____
Odors (perfume, shaving lotion, etc.)	_____	_____
Cigarette smoke	_____	_____
Taking pain medicine	_____	_____
Watching someone else vomit	_____	_____
Sight of blood	_____	_____
Food items (e.g., eggs)	_____	_____
Surgery	_____	_____
Other	_____	_____

STAI-T

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you *generally* feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

		Almost Never	Sometimes	Often	Almost Always
21.	I feel pleasant	1	2	3	4
22.	I feel nervous and restless	1	2	3	4
23.	I feel satisfied	1	2	3	4
24.	I wish I could be as happy as others seem to be	1	2	3	4
25.	I feel like a failure	1	2	3	4
26.	I feel rested	1	2	3	4
27.	I am, "calm, cool, and collected"	1	2	3	4
28.	I feel that difficulties are piling up so that I cannot overcome them	1	2	3	4
29.	I worry too much over something that really doesn't matter	1	2	3	4
30.	I am happy	1	2	3	4
31.	I have disturbing thoughts	1	2	3	4
32.	I lack self-confidence	1	2	3	4
33.	I feel secure	1	2	3	4
34.	I make decisions easily	1	2	3	4
35.	I feel inadequate	1	2	3	4
36.	I am content	1	2	3	4
37.	Some unimportant thought runs through my mind and bothers me	1	2	3	4
38.	I take disappointments so keenly that I can't put them out of my mind	1	2	3	4
39.	I am a steady person	1	2	3	4
40.	I get in a state of tension or turmoil as I think over my recent concerns and interests	1	2	3	4

Facit-F (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	Emotional Well-Being	Not at all	A little bit	Some-what	Quite a bit	Very much
1.	I feel sad	0	1	2	3	4
2.	I am satisfied with how I am coping with my illness	0	1	2	3	4
3.	I am losing hope in the fight against my illness	0	1	2	3	4
4.	I feel nervous	0	1	2	3	4
5.	I worry about dying	0	1	2	3	4
6.	I worry that my condition will get worse	0	1	2	3	4

	Functional Well-Being	Not at all	A little bit	Some-what	Quite a bit	Very much
1.	I am able to work (including at home)	0	1	2	3	4
2.	My work (include work at home) is fulfilling	0	1	2	3	4
3.	I am able to enjoy life	0	1	2	3	4
4.	I have accepted my illness	0	1	2	3	4
5.	I am sleeping well	0	1	2	3	4
6.	I am enjoying the things I usually do for fun	0	1	2	3	4
7.	I am content with the quality of my life right now	0	1	2	3	4

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Facit-F (Version 4)

Below is a list of statements that other people with your illness have said are important. **By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.**

	Physical Well-Being	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
1.	I have a lack of energy	0	1	2	3	4
2.	I have nausea	0	1	2	3	4
3.	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
4.	I have pain	0	1	2	3	4
5.	I am bothered by side effects of treatment	0	1	2	3	4
6.	I feel ill	0	1	2	3	4
7.	I am forced to spend time in bed	0	1	2	3	4

	Social/Family Well-Being	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
1.	I feel close to my friends	0	1	2	3	4
2.	I get emotional support from my family	0	1	2	3	4
3.	I get support from my friends	0	1	2	3	4
4.	My family has accepted my illness	0	1	2	3	4
5.	I am satisfied with family communication about my illness	0	1	2	3	4
6.	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box ☐ *and go to the next section*	0	1	2	3	4
7.	I am satisfied with my sex life	0	1	2	3	4

Facit-F (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	Additional concerns	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
1.	I have been short of breath	0	1	2	3	4
2.	I am self-conscious about the way I dress.	0	1	2	3	4
3.	One or more of my arms are swollen or tender.	0	1	2	3	4
4.	I feel sexually attractive.	0	1	2	3	4
5.	I am bothered by hair loss.	0	1	2	3	4
6.	I worry that other members of my family might someday get the same illness I have.	0	1	2	3	4
7.	I worry about the effect of stress on my illness.	0	1	2	3	4
8.	I am bothered by a change in weight.	0	1	2	3	4
9.	I am able to feel like a woman.	0	1	2	3	4

ID#_____ Date_____ 12

POMS T/D- Short Version

Below is a list of words that describe feelings people have. Please read each one carefully. Then CIRCLE ONE number which best describes **HOW YOU HAVE BEEN FEELING IN THE PAST WEEK.**

The numbers refer to these phrases:
0 = Not at all
1 = A little
2 = Moderately
3 = Quite a bit
4 = Extremely

1	Tense	0	1	2	3	4	20	Annoyed	0	1	2	3	4
2	Angry	0	1	2	3	4	21	Discouraged	0	1	2	3	4
3	Worn out	0	1	2	3	4	22	Resentful	0	1	2	3	4
4	Unhappy	0	1	2	3	4	23	Nervous	0	1	2	3	4
5	Lively	0	1	2	3	4	24	Miserable	0	1	2	3	4
6	Confused	0	1	2	3	4	25	Cheerful	0	1	2	3	4
7	Peeved	0	1	2	3	4	26	Bitter	0	1	2	3	4
8	Sad	0	1	2	3	4	27	Exhausted	0	1	2	3	4
9	Active	0	1	2	3	4	28	Anxious	0	1	2	3	4
10	On edge	0	1	2	3	4	29	Helpless	0	1	2	3	4
11	Grouchy	0	1	2	3	4	30	Weary	0	1	2	3	4
12	Blue	0	1	2	3	4	31	Bewildered	0	1	2	3	4
13	Energetic	0	1	2	3	4	32	Furious	0	1	2	3	4
14	Hopeless	0	1	2	3	4	33	Full of pep	0	1	2	3	4
15	Uneasy	0	1	2	3	4	34	Worthless	0	1	2	3	4
16	Restless	0	1	2	3	4	35	Forgetful	0	1	2	3	4
17	Unable to concentrate	0	1	2	3	4	36	Vigorous	0	1	2	3	4
18	Fatigued	0	1	2	3	4	37	Uncertain about things	0	1	2	3	4
19	Bushed	0	1	2	3	4							

On your day of surgery, how emotionally upset do you think you will feel?

Please put a slash through this line to indicate how upset you expect to feel.

Not At Upset _____ As Upset As I Could Be

After surgery, how emotionally upset do you think you will feel?

Please put a slash through this line to indicate how upset you expect to feel.

Not At All Upset _____ As Upset As I Could Be

On your day of surgery, how much pain do you think you will feel?

Please put a slash through this line to indicate how much pain you expect to feel.

No Pain At All _____ As Much Pain As There Could Be

After surgery, how much pain do you think you will feel?

Please put a slash through this line to indicate how much pain you expect to feel.

No Pain At All _____ As much pain as There Could Be

How emotionally upset do you feel right now?

Please put a slash through this line to indicate how upset you feel.

Not At All Upset _____ As Upset As I Could Be

After surgery, how nauseated do you think you will feel?

Please put a slash through this line to indicate how nauseated you expect to feel.

Not At All Nauseated _____ As Nauseated As I Could Be

END of pre-session questionnaire

STUDY ID# _____ HOSPITAL # _____

DO NOT WRITE ABOVE THIS LINE

Brief Pain Inventory (Short Form)

Date: _____/_____/_____ Time: _____

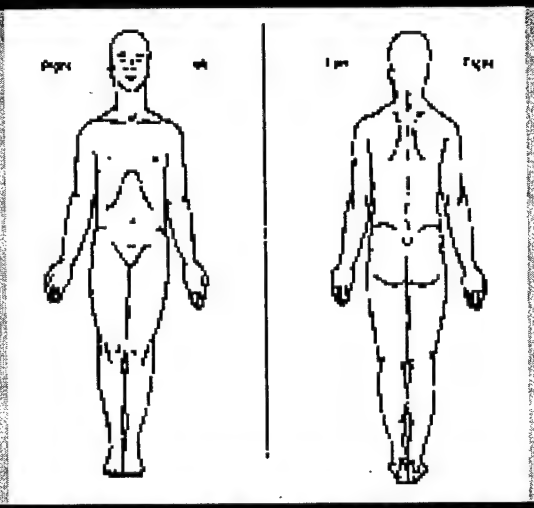
Name: _____ _____ _____

Last First Middlle Initial

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one nuimber that best describes your pain at its least in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No Relief										Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

C. Walking Ability

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

Pre-Surgery Questionnaire Packet

ID# _____

Date ___/___/___

POMS T/D- Short Version

Below is a list of words that describe feelings people have. Please read each one carefully. Then CIRCLE ONE number which best describes **HOW YOU HAVE BEEN FEELING IN THE PAST WEEK.**

The numbers refer to these phrases:
0 = Not at all
1 = A little
2 = Moderately
3 = Quite a bit
4 = Extremely

1	Tense	0	1	2	3	4	20	Annoyed	0	1	2	3	4
2	Angry	0	1	2	3	4	21	Discouraged	0	1	2	3	4
3	Worn out	0	1	2	3	4	22	Resentful	0	1	2	3	4
4	Unhappy	0	1	2	3	4	23	Nervous	0	1	2	3	4
5	Lively	0	1	2	3	4	24	Miserable	0	1	2	3	4
6	Confused	0	1	2	3	4	25	Cheerful	0	1	2	3	4
7	Peeved	0	1	2	3	4	26	Bitter	0	1	2	3	4
8	Sad	0	1	2	3	4	27	Exhausted	0	1	2	3	4
9	Active	0	1	2	3	4	28	Anxious	0	1	2	3	4
10	On edge	0	1	2	3	4	29	Helpless	0	1	2	3	4
11	Grouchy	0	1	2	3	4	30	Weary	0	1	2	3	4
12	Blue	0	1	2	3	4	31	Bewildered	0	1	2	3	4
13	Energetic	0	1	2	3	4	32	Furious	0	1	2	3	4
14	Hopeless	0	1	2	3	4	33	Full of pep	0	1	2	3	4
15	Uneasy	0	1	2	3	4	34	Worthless	0	1	2	3	4
16	Restless	0	1	2	3	4	35	Forgetful	0	1	2	3	4
17	Unable to concentrate	0	1	2	3	4	36	Vigorous	0	1	2	3	4
18	Fatigued	0	1	2	3	4	37	Uncertain about things	0	1	2	3	4
19	Bushed	0	1	2	3	4							

On your day of surgery, how emotionally upset do you think you will feel?

Please put a slash through this line to indicate how upset you expect to feel.

Not At Upset _____ As Upset As I Could Be

After surgery, how emotionally upset do you think you will feel?

Please put a slash through this line to indicate how upset you expect to feel.

Not At All Upset _____ As Upset As I Could Be

On your day of surgery, how much pain do you think you will feel?

Please put a slash through this line to indicate how much pain you expect to feel.

No Pain At All _____ As much pain as There Could Be

After surgery, how much pain do you think you will feel?

Please put a slash through this line to indicate how much pain you expect to feel.

No Pain At All _____ As much pain as There Could Be

How emotionally upset do you feel right now?

Please put a slash through this line to indicate how upset you feel.

Not At All Upset _____ As Upset As I Could Be

After surgery, how nauseated do you think you will feel?

Please put a slash through this line to indicate how nauseated you expect to feel.

Not At All Nauseated _____ As Nauseated As I Could Be

END of pre-session questionnaire

Post-Surgery Day Assessment

ID# _____

Date ___/___/___

MEMORIAL SYMPTOM ASSESSMENT SCALE - Part 1

ID: DATE:

INSTRUCTIONS: We have listed 24 symptoms below. Read each one carefully. If you have had the symptom since surgery, let us know how OFTEN you had it how SEVERE it was usually and how much it DISTRESSED OR BOTHERED you by circling the appropriate number. If you DID NOT HAVE the symptom, make an "X" in the box marked "DID NOT HAVE".

SINCE YOUR SURGERY Did you have any of the following symptoms?	DID NOT HAVE	IF YES, How OFTEN did you have it?				IF YES, How SEVERE was it usually?				IF YES, How much did it DISTRESS or BOTHER you?				
		Rarely	Occasionally	Frequently	Almost	Slight	Moderate	Severe	Very Severe	Not at all	A little bit	Somewhat	Quite a bit	Very much
Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling nervous		1	2	3	4	1	2	3	4	0	1	2	3	4
Nausea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling drowsy		1	2	3	4	1	2	3	4	0	1	2	3	4
Vomiting		1	2	3	4	1	2	3	4	0	1	2	3	4
Problems with urination		1	2	3	4	1	2	3	4	0	1	2	3	4
Appetite		1	2	3	4	1	2	3	4	0	1	2	3	4
Diarrhea		1	2	3	4	1	2	3	4	0	1	2	3	4
Sad		1	2	3	4	1	2	3	4	0	1	2	3	4

POST SURGERY DAY ASSESSMENT

1. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

2. Please rate your nausea by circling the one number that tells how much nausea you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Nausea										Nausea as bad as you can imagine

3. Please rate how unpleasant your pain is by circling the one number that tells how unpleasant your pain is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

Daily Questionnaire

ID# _____

Date ___/___/___

Phone Sheet

Today's Date: _____ ID: _____

Please complete a new sheet each day just before you go to bed.

1. Medications: Please indicate the Name of Medication, Time you took it, and Reason for taking it.

Medication Name	Amount (e.g. number of pills size of pills	Time Taken	Reason for Taking

2. Please rate your pain by circling the one number that tells how much pain you have right now.

0 1 2 3 4 5 6 7 8 9 10

No Pain — Pain as intense as you can imagine

3. Please rate your nausea by circling the one number that tells how much nausea you have right now.

0 1 2 3 4 5 6 7 8 9 10

No Nausea — Nausea as bad as you can imagine

4. Please rate how unpleasant your pain is by circling the one number that tells how unpleasant your pain is right now.

0 1 2 3 4 5 6 7 8 9 10

Not at all Unpleasant — As Unpleasant as you can imagine

MEMORIAL SYMPTOM ASSESSMENT SCALE - Part 1

ID: DATE:

INSTRUCTIONS: We have listed 24 symptoms below. Read each one carefully. If you have had the symptom since surgery, let us know how OFTEN you had it how SEVERE it was usually and how much it DISTRESSED OR BOTHERED you by circling the appropriate number. If you DID NOT HAVE the symptom, make an "X" in the box marked "DID NOT HAVE".

SINCE YOUR SURGERY Did you have any of the following symptoms?	DID NOT HAVE	IF YES, How OFTEN did you have it?				IF YES, How SEVERE was it usually?				IF YES, How much did it DISTRESS or BOTHER you?				
		Rarely	Occasionally	Frequently	Almost	Slight	Moderate	Severe	Very Severe	Not at all	A little bit	Somewhat	Quite a bit	Very much
Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling nervous		1	2	3	4	1	2	3	4	0	1	2	3	4
Nausea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling drowsy		1	2	3	4	1	2	3	4	0	1	2	3	4
Vomiting		1	2	3	4	1	2	3	4	0	1	2	3	4
Problems with urination		1	2	3	4	1	2	3	4	0	1	2	3	4
Appetite		1	2	3	4	1	2	3	4	0	1	2	3	4
Diarrhea		1	2	3	4	1	2	3	4	0	1	2	3	4
Sad		1	2	3	4	1	2	3	4	0	1	2	3	4

STUDY ID# _____ HOSPITAL # _____

DO NOT WRITE ABOVE THIS LINE

Brief Pain Inventory (Short Form)

Date: _____/_____/_____ Time: _____

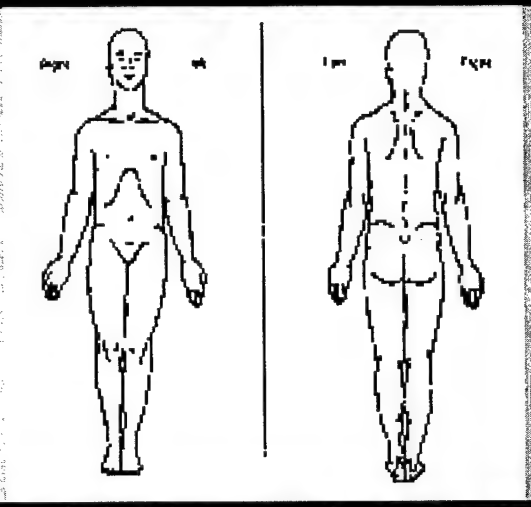
Name: _____ _____ _____

Last First Middlle Initial

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10

No Pain — Pain as bad as you can imagine

4. Please rate your pain by circling the one nuimber that best describes your pain at its least in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10

No Pain — Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0 1 2 3 4 5 6 7 8 9 10

No Pain — Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0 1 2 3 4 5 6 7 8 9 10

No Pain — Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No Relief										Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

C. Walking Ability

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

POST SURGERY PACKET

1- WEEK

ID# _____

Date ___/___/___

MEMORIAL SYMPTOM ASSESSMENT SCALE - Part 1

ID: DATE:

INSTRUCTIONS: We have listed 24 symptoms below. Read each one carefully. If you have had the symptom since surgery, let us know how OFTEN you had it how SEVERE it was usually and how much it DISTRESSED OR BOTHERED you by circling the appropriate number. If you DID NOT HAVE the symptom, make an "X" in the box marked "DID NOT HAVE".

SINCE YOUR SURGERY Did you have any of the following symptoms?	DID NOT HAVE	IF YES, How OFTEN did you have it?				IF YES, How SEVERE was it usually?				IF YES, How much did it DISTRESS or BOTHER you?				
		Rarely	Occasionally	Frequently	Almost	Slight	Moderate	Severe	Very Severe	Not at all	A little bit	Somewhat	Quite a bit	Very much
Difficulty concentrating		1	2	3	4	1	2	3	4	0	1	2	3	4
Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
Cough		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling nervous		1	2	3	4	1	2	3	4	0	1	2	3	4
Dry mouth		1	2	3	4	1	2	3	4	0	1	2	3	4
Nausea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling drowsy		1	2	3	4	1	2	3	4	0	1	2	3	4
Numbness/tingling in hands/feet		1	2	3	4	1	2	3	4	0	1	2	3	4
Difficulty sleeping		1	2	3	4	1	2	3	4	0	1	2	3	4
Vomiting		1	2	3	4	1	2	3	4	0	1	2	3	4
Problems with urination		1	2	3	4	1	2	3	4	0	1	2	3	4
Appetite		1	2	3	4	1	2	3	4	0	1	2	3	4
Diarrhea		1	2	3	4	1	2	3	4	0	1	2	3	4
Sad		1	2	3	4	1	2	3	4	0	1	2	3	4
Worrying		1	2	3	4	1	2	3	4	0	1	2	3	4
Dizziness		1	2	3	4	1	2	3	4	0	1	2	3	4

Today's Date: _____ Time: _____ ID: _____

Please complete this form to indicate the medications that you have taken since your surgery.

1. Medications: Please indicate the Name of Medication, Time you took it, and Reason for taking it.

Medication Name	Amount (e.g. number of pills size of pills	Date & Time Taken	Reason for Taking

1. Please rate your pain by circling the one number that tells how much pain you have right now.

0 1 2 3 4 5 6 7 8 9 10

No Pain — Pain as bad as you can imagine

2. Please rate your nausea by circling the one number that tells how much nausea you have right now.

0 1 2 3 4 5 6 7 8 9 10

No Nausea — Nausea as bad as you can imagine

3. Please rate how unpleasant your pain is by circling the one number that tells how unpleasant your pain is right now.

0 1 2 3 4 5 6 7 8 9 10

Not at all Unpleasant — As Unpleasant as you can imagine

Facit (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	Emotional Well-Being	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
1.	**I feel sad**	**0**	**1**	**2**	**3**	**4**
2.	**I am satisfied with how I am coping with my illness**	**0**	**1**	**2**	**3**	**4**
3.	**I am losing hope in the fight against my illness**	**0**	**1**	**2**	**3**	**4**
4.	**I feel nervous**	**0**	**1**	**2**	**3**	**4**
5.	**I worry about dying**	**0**	**1**	**2**	**3**	**4**
6.	**I worry that my condition will get worse**	**0**	**1**	**2**	**3**	**4**

	Functional Well-Being	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
1.	I am able to work (including at home)	0	1	2	3	4
2.	My work (include work at home) is fulfilling	0	1	2	3	4
3.	I am able to enjoy life	0	1	2	3	4
4.	I have accepted my illness	0	1	2	3	4
5.	I am sleeping well	0	1	2	3	4
6.	I am enjoying the things I usually do for fun	0	1	2	3	4
7.	I am content with the quality of my life right now	0	1	2	3	4

Facit (Version 4)

Below is a list of statements that other people with your illness have said are important. **By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.**

	Physical Well-Being	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
1.	I have a lack of energy	0	1	2	3	4
2.	I have nausea	0	1	2	3	4
3.	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
4.	I have pain	0	1	2	3	4
5.	I am bothered by side effects of treatment	0	1	2	3	4
6.	I feel ill	0	1	2	3	4
7.	I am forced to spend time in bed	0	1	2	3	4

	Social/Family Well-Being	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
1.	I feel close to my friends	0	1	2	3	4
2.	I get emotional support from my family	0	1	2	3	4
3.	I get support from my friends	0	1	2	3	4
4.	My family has accepted my illness	0	1	2	3	4
5.	I am satisfied with family communication about my illness	0	1	2	3	4
6.	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box ☐ *and go to the next section*	0	1	2	3	4
7.	I am satisfied with my sex life	0	1	2	3	4

Facit (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	Additional concerns	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
1.	I have been short of breath	0	1	2	3	4
2.	I am self-conscious about the way I dress.	0	1	2	3	4
3.	One or more of my arms are swollen or tender.	0	1	2	3	4
4.	I feel sexually attractive.	0	1	2	3	4
5.	I am bothered by hair loss.	0	1	2	3	4
6.	I worry that other members of my family might someday get the same illness I have.	0	1	2	3	4
7.	I worry about the effect of stress on my illness.	0	1	2	3	4
8.	I am bothered by a change in weight.	0	1	2	3	4
9.	I am able to feel like a woman.	0	1	2	3	4

POMS T/D- Short Version

Below is a list of words that describe feelings people have. Please read each one carefully. Then CIRCLE ONE number which best describes **HOW YOU HAVE BEEN FEELING IN THE PAST WEEK.**

The numbers refer to these phrases:
0 = Not at all
1 = A little
2 = Moderately
3 = Quite a bit
4 = Extremely

1	Tense	0	1	2	3	4	20	Annoyed	0	1	2	3	4
2	Angry	0	1	2	3	4	21	Discouraged	0	1	2	3	4
3	Worn out	0	1	2	3	4	22	Resentful	0	1	2	3	4
4	Unhappy	0	1	2	3	4	23	Nervous	0	1	2	3	4
5	Lively	0	1	2	3	4	24	Miserable	0	1	2	3	4
6	Confused	0	1	2	3	4	25	Cheerful	0	1	2	3	4
7	Peeved	0	1	2	3	4	26	Bitter	0	1	2	3	4
8	Sad	0	1	2	3	4	27	Exhausted	0	1	2	3	4
9	Active	0	1	2	3	4	28	Anxious	0	1	2	3	4
10	On edge	0	1	2	3	4	29	Helpless	0	1	2	3	4
11	Grouchy	0	1	2	3	4	30	Weary	0	1	2	3	4
12	Blue	0	1	2	3	4	31	Bewildered	0	1	2	3	4
13	Energetic	0	1	2	3	4	32	Furious	0	1	2	3	4
14	Hopeless	0	1	2	3	4	33	Full of pep	0	1	2	3	4
15	Uneasy	0	1	2	3	4	34	Worthless	0	1	2	3	4
16	Restless	0	1	2	3	4	35	Forgetful	0	1	2	3	4
17	Unable to concentrate	0	1	2	3	4	36	Vigorous	0	1	2	3	4
18	Fatigued	0	1	2	3	4	37	Uncertain about things	0	1	2	3	4
19	Bushed	0	1	2	3	4							

Patient Satisfaction Questionnaire

Please indicate your answers by checking the appropriate box.

Overall, how would you rate your satisfaction with:

		Excellent	Very Good	Good	Fair	Poor
1.	The care you received during your hospital stay?					
2	The anesthesia used for your surgery?					
3	The care provided by your doctors during your hospital stay?					
4	The treatment of any pain or discomfort you had during your hospital stay?					
5	The treatment of any nausea and vomiting you had during your hospital stay?					
6	The care you received at home since your hospital stay?					
7	The treatment of any pain or discomfort you've had since you have been home?					
8	The treatment of any nausea or vomiting you've had since you have been home?					
9	Discharge instructions: how clearly and completely you were told what to do and what to expect when you left the hospital?					
10	Coordination of care after discharge: Hospital staff's efforts to prepare you for your recovery at home (i.e., instructions for wound care, emptying of drains, medications, follow-up appointments)?					
11	Your overall care?					

		A lot shorter than I needed	A little shorter than I needed	About Right	A little longer than I needed	A lot longer than I needed
12.	Do you think the amount of time you spent in the hospital was?					

NAUSEA QUESTIONNAIRE

Please check the appropriate box to indicate how nauseated you felt at each time by entering the appropriate number according to the following scale:

1	2	3	4	5	6	7
Not at all Nauseated			Moderately Nauseated			Extremely Nauseated

	Day of Surgery	1st Day Following Surgery	2nd Day Following Surgery	3rd Day Following Surgery	4th Day Following Surgery	5th Day Following Surgery
Morning						
Afternoon						
Evening						
Nighttime						